TRANSDERMAL NITROGLYCERINE VERSUS ORAL NIFEDIPINE ADMINISTRATION FOR TOCOLYSIS IN PRETERM LABOUR

DISSERTATION SUBMITTED FOR

M.D . (BRANCH – II)

(OBSTETRICS & GYNAECOLOGY)

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BONAFIDE CERTIFICATE

This is to certify that the dissertation entitled **"TRANSDERMAL NITROGLYCERINE VERSUS ORAL NIFEDIPINE ADMINISTRATION FOR TOCOLYSIS IN PRETERM LABOUR"** submitted by **Dr.K.KAMESWARI** to the Tamilnadu Dr. M.G.R Medical University, Chennai, in partial fulfillment of the requirement for the award of M.D. Degree Branch – II (OBSTETRICS & GYNAECOLOGY) is a bonafide research work carried out by her under direct supervision & guidance.

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DECLARATION

I, **Dr.K.KAMESWARI** declare that, I carried out this work on **TRANSDERMAL NITROGLYCERINE VERSUS ORAL NIFEDIPINE ADMINISTRATION FOR TOCOLYSIS IN PRETERM LABOUR"** at the Department of Obstetrics & Gynaecology, Madurai Medical College, I also declare that this bonafide work or a part of this work was not submitted by me or any others for any award, degree, or diploma to any other University, Board, either in India or abroad.

This is submitted to the Tamilnadu Dr. M.G.R. Medical University, Chennai in partial fulfillment of the rules and regulations for the M.D Degree examination in (Branch II) Obstetrics & Gynaecology , to be held in April 2012 .

Place : Madurai **Dr.K.KAMESWARI**
Date :

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CONTENTS

TRANSDERMAL NITROGLYCERINE VERSUS ORAL NIFEDIPINE ADMINISTRATION FOR TOCOLYSIS IN PRETERM LABOUR

ABSTRACT

Objective

Comparison of oral nifedipine and transdermal nitroglycerin for tocolysis in preterm labour in the following effects, acute tocolytic effect, duration of prolongation of pregnancy , neonatal outcome.

Materials and methods

Study on tocolysis in preterm labour was conducted in Government Rajaji Hospital from December 2010 to November 2011. 100 women with preterm labour randomly selected from the pregnant women attending antenatal OP and from labour ward from the department of obstetrics and gynecology. Out of which 50 women were recruited for oral nifedipine (initially 20mg , followed by 10mg till the contractions stop) and another 50 women were recruited for transdermal nitroglycerin patch (25 mg, directly applied over the skin of the abdomen).

Inclusion criteria :

Woman with singleton pregnancy with preterm labour from 28 – 36 weeks of gestation were selected for this study.

Exclusion criteria:

Pregnant women with preterm labour with premature rupture of membranes, fetal distress , major fetal congenital anomalies , chorioamnionitis antepartum hemorrhage , sensitivity or contra indication to nifedipine/nitrates, were excluded from this study .

Results

In both the groups time needed for tocolysis ranged from 2-12 hours . Mean time needed for tocolysis in group I was 4.55 hours and with group II , it was 6.09 hours . when acute tocolytic effect (Prolongation of pregnancy beyond 48 hours) was considered , it was 45 women in group I and 36 women in group II. Mean duration of Prolongation of pregnancy with group I was 20.74 days and with group II , it was 13.5 days . In group I 7 babies got admitted in new born ward , 16 babies in group II got admitted in new born ward .

Conclusion

When compared with nitroglycerin , nifedipine is found to be safe and successful in achieving complete tocolysis and also effective in prolongation of pregnancy . Nifedipine has minimal maternal side effects and better neonatal outcome.

Key word

Preterm labour , Oral nifedipine , glyceryltrinitrate transdermal patch

INTRODUCTION

The World health organization has estimated that 12.9. million births (or) 9.6% of all births world wide, were preterm in 2005.

In the era of modern obstetrics, despite advancement in all specialities, the delivery of infants in preterm period of gestation is a major factor contributing to perinatal mortality and morbidity. Incidence of preterm birth is about 10-15% . Prematurity contributes also to the reduced quality of life and neurosensory disability which increases with decreasing gestational age. Preterm birth may have huge psychosocial and emotional effects on the family, as well as being costly for health services.

Preterm labour is defined by the world health organization as the onset of labour, in a pregnancy before the completion of 37 weeks of gestation and after 20 weeks of gestation. As per ACOG criteria (1997) Preterm labour is defined as the occurrence of regular uterine contractions (four or more in 20 minutes (or) eight (or) more in 1 hour) and with cervical changes (effacement equal to (or) more than 80% and dilatation equal to (or) greater than 1cm). Lower limit of surivial is 24 weeks of gestation in western countries and it is more than 32 weeks in India. Upper limit of prematurity is 36 weeks.

In about 45-50% of cases of preterm labour the etiology remains obscure. So attempts at prevention have not been very encouraging, but arrest of preterm labour continues to be the need of the hour. Obstetrician faces the challenge of survival of permature neonate as well as therapeutic alternatives available for management of preterm labour.

The aim of care around preterm birth does not always involve prevention of preterm labour and birth. In situation, where clinical considerations make it desirable to prolong pregnancy, the primary outcome considered is time gained to

- Seek advise from perinatal care
- Institute therapy to improve lung maturity
- If necessary move the mother to a centre with neonatal intensive care facilities.

Currently main goal for use of tocolytic therapy is to delay the birth so as to allow the use of corticosteroids for acclerating fetal lung maturity and maternal transfer to a tertiary care center and there by reducing neonatal morbidity and mortality. By arresting preterm labour, we can reduce the maternal guilt and anxiety about the cause for preterm birth of their baby and financial burden of preterm birth and care around preterm birth for families and communities.

There are many number of tocolytic drugs, but unfortunately , none has been completely effective, because of questionable efficacy and potentially serious side effects out weigh the use of many tocolytic agents. Beta adrenergic receptor agonists like Ritodrine , Terbutaline , Isoxsuprine and others like magnesium sulphate , calcium channel blockers (nifedipine) Prostaglandin synthase inhibitors (Indomethacin), nitricoxide donors (glyceryl trinitrate) are tocolytic agents in use. In this study, comparison of effectiveness of oral nifedipine with transdermal nitroglycerin in the inhibition of preterm delivery is being done.

AIM OF THE STUDY

Comparison of oral nifedipine and transdermal nitroglycerin for tocolysis in preterm labour in the following effects:

1. Acute tocolytic effect
2. Duration of prolongation of pregnancy
3. Neonatal outcome

REVIEW OF LITERATURE

Preterm labour is a syndrome accounts for 45-50% of all preterm birth. Despite advances in perinatal medicine in recent decades, the problem of preterm delivery continues to frustrate satisfactory reproductive outcome.

Preterm labour is defined as the occurrence of regular uterine contractions (four or more in 20 minutes (or) eight (or) more in 1 hour) and cervical changes (effacement equal to (or) more than 80% and dilatation equal to (or) greater than 1cm) in women with intact fetal membranes and gestational age less than 37 weeks, as per ACOG criteria (1997). Currently however such clinical findings are now considered inaccurate predictors of preterm delivery (ACOG 2003). Thus such explicit criteria do not appear in more recent guide lines (ACOG 2008) .

The pathogenesis of preterm labour may be

- ✓ Progesterone withdrawl
- ✓ Oxytocin initiation
- ✓ Decidual activation

Preterm labour may be characterised by the premature activation of final pathway of parturition. It can be induced by infection, maternal

(or) fetal stress, choriodecidual bleeding, abnormal placentation – all will ultimately induce the release of inflammatory cytokines such as IL–6, IL-8, TNF alpha that will in turn , can cause myometrial activation, membrane activation , cervical ripening, that is the common pathway of parturition.

Premature ripening of the cervix is the predominant feature in women with incompetent cervix, premature activation of membranes is the key event, in women with premature rupture of membranes and premature activation of myometrium is the cardinal feature in women with preterm labour and intact membranes . During normal pregnancy, the uterus is under the effect of a series of inhibitors of uterine contractions, such as progesterone, relaxin, nitric oxide and prostacyclin. The production of uterine contractions requires an increase in myometrial intra cellular calcium concentration. Calcium will bind to calmodulin and Calcium - calmodulin complex bind with enzyme myosin light chain kinase and phosphorylate the short chain of myosin and by production of ATP causes muscle contraction.

Preterm labour can be classified into

- Advanced Preterm labour – if cervix effaced more than 80% and dilated more than 3cm .
- Early preterm labour – when cervix effaced more than 80% and dilated more than 1cm but less than 3cm.

- Threatened preterm labour - cervix effaced less than 80% and dilated less than 1cm with cervical length less than 2.5cm.

Prematurity may be classified according to gestational age into 3 groups.

Severe prematurity – when birth occurs before 30 weeks.

Intermediate prematurity – when birth occurs between 30 -34 weeks

Late (or) mild prematurity – between 34 and 37 weeks.

All the obstetrical resources should be used to avoid severe and intermediate prematurity and these births should occur in tertiary care centers with adequate neonatal intensive care facilities . Mild prematurity can be managed in hospitals with level II nurseries.

From 26 – 34 weeks of gestation , the incidence of major neonatal morbidity ranged from 20 to 60% for Respiratory Distress syndrome, 15-50% for patentductus arteriosus, 5 – 30% for sepsis and 2-25% for necrotising enterocolitis other insults are intraventricular Hemorrhage, periventricular leucomalacia and retinopathy of prematurity . Longterm morbidity are cerebral palsy, blindness, refractory errors, hearing loss, intellectual impairments, behavioural problem, longterm respiratory ill health – broncho pulmonary dysplasia, other neurological disabilities.

There are number of drugs available for the acute treatment of preterm labour, to suppress the uterine activity, with different

pharmacological principles. A satisfactory pharmacological method for the prevention of treatment of preterm labour is yet to be found. Since tocolysis have both potential benefit and side effects to the neonate and mother, their use should be based on well designed, controlled clinical studies. Tocolysis may be considered for women with suspected preterm labour who have had an otherwise uncomplicated pregnancy. A more recent meta analysis serves to confirm findings from earlier randomised clinical trials showing that maintenance therapy did not influence outcome in terms of incidence of preterm delivery.

The following conditions are needed for the use of tocolytic therapy.

Criteria for Tocolysis are :

1) Presence of regular uterine contractions with evidence of changes in cervix.
2) A gestational age (24-36 weeks) at which treatment will benefit the fetus.
3) The maternal and fetal benefits must outweigh the risks and side effects of tocolytic use.
4) Absence of medical/ obstetrical contra indications to inhibition of labour (or) use of tocolytics.

Continuation of Pregnancy is contraindicated in the following conditions

Contraindications to tocolysis are :

1) Intra uterine fetal death
2) Fetal distress /congenital anomaly
3) Chorioamnionitis
4) Severe intra uterine growth restriction
5) Severe (or) undiagnosed maternal vaginal bleeding
6) Eclampsia (or) severe pre eclampsia
7) Premature rupture of membranes.

If any of the above conditions are present, pregnancy is terminated as early as possible.

Pharmacological agents available at present

Tocolytic agents currently utilised for treating preterm labour include,

1. Beta adrenergic receptor agonist (Isoxsuprine /Ritodrine/ Terbutaline)
2. Magnesium sulphate
3. Calcium channel blockers (nifedipine)
4. Oxytocin receptor antagonists
5. Prostaglandin synthase inhibitors (Indomethacin)
6. Nitric oxide donors (glyceryl trinitrate)

1. Beta adrenergic receptor agonists :

a) Isox suprine :

Isox suprine was first introduced in the management of preterm labour in 1961 (Bishop and wouteriz). It was the first Beta mimetic agent to be studied ; Due to its cardiac side effects and failed to show any benefit in either prolonging the pregnancy (or) reducing the perinatal mortality, this drug is not much used in arrest of preterm labour.

b) Ritodrine :

Any Beta2 sympathomimetic drug is relatively, but not completely specific for Beta 2 rather than the Beta 1 receptor. Ritodrine is used as IV infusion with 5% dextrose, because of risk of sodium which can cause water retention, it is not used with normal saline. Nausea , vomiting, tremor , palpitation, nervousness, restlessness, are frequently reported, as side effects of ritodrine. Pulmary edema is more fatal complication of this drug.

c) Terbutaline :

Terbutaline was commonly used previously , like ritodrine it can cause pulmonary edema. When longterm terbutaline given by subcutaneous pump, can cause sudden maternal death and myocardial necrosis in neonate, when it is used for 12 weeks. Oral terbutaline

therapy to prevent preterm delivery has also not been effective . Terbutaline did not significantly prolong pregnancy , prevent preterm delivery (or) improve neonatal outcome.

2) Magnesium Sulphate :

Magnesium sulphate is most commonly used for the prevention of treatment of seizures associated with preeclampsia but its tocolytic effect has been recognised since 1959. The therapeutic level ranged for both these indications is plasma concentration of 4-8 mmol-L. Higher concentration than this, produce neuromuscular blockage, respiratory depression and cardiac arrest. Further more, it crosses the placenta, and the new born may be drowsy and exhibit decreased muscle tone at delivery resulting in hypoventilation requiring assisted ventilation. Longterm administration can case fetal/neonatal hypocalcemia.

3) Calcium Channel Blockers : (nifedipine)

Myometrial activity is directly related to cytoplasmic free calcium and reduction in its concentrations inhibits contractions. Calcium channel blockers, act to inhibit by a variety of mechanisms, the entry of calcium through channels in the cell membranes. Although they were developed to treat hypertension, their use to arrest preterm labour has been the subject to research since the late 1970s. There are fewer maternal side effects like flushing, headache, dizziness, palpitation and no apparent fetal effects. In (1997) papatsonis etal and In (2002) king et

al, in recent meta analysis of comparing nifedipine with Ritodrine for the treatment of preterm labour – suggested that nifedipine is more effective in delaying delivery and is associated with reduced NICU admission . Studies on nifedipine was conducted by Ganla (1999) India it was used for 26-36 weeks of gestational age. In carr (1999) United States – recruited the patient in 24-33 weeks of gestational age. Sayin (2004) Turkey study conducted in women with singleton (or) twin pregnancy and intact membranes who had been in active preterm labour. Amorim (2009) Brazil taken the women with 24 -34 weeks of gestational age for study. In this study comparative study of oral nifedipine with transdermal nitroglycerin patch was done. A systematic review using adjusted indirect comparison between nifedpine and atosiban concluded that nifedipine was associated with a non significant trend towards increased delay in delivery by 48 hours , in cochrane review.

4) Oxytocin receptor antagonist : (Atosiban)

In humans , the myometrium becomes increasingly sensitive to oxytocin , because of increased oxytocin receptor activity mainly in late pregnancy, and it is also shown following the onset of preterm labour. (Takahashi etal – 1980)

Atosiban is nonapeptide oxytocin analog, competitive antagonist of oxytocin induced contractions. A data from (Romero etal 2000)

implies that atosiban can delay delivery when compared to placebo. In 2004, Goodwin reviewed the efficacy of atosiban, and it is widely used for tocolysis.

5. Prostaglandin synthase inhibitors (Indomethacin)

Drugs that inhibit prostaglandins have been of considerable interest because prostaglandins are intimately involved in contractions of normal labour. These drugs previously suggested for as an alternative to beta adrenergic agonists for inhibition of preterm labour, particularly in patient with cardiac disese (or) hyper thyroidism. They are not used because of fear of premature closure of ductus arteriosus pulmonary Hypertension and necrotising enterocolitis in the fetus.

6. Nitric Oxide donors :

Nitric oxide is endogenously occuring bio molecule and can be given in the form of nitric oxide donor. The first recorded use of an nitric oxide donor in pregnancy was reported in British Journal 1882, when Amyl nitrate was used to deliver, morbidly adherent placenta.

Glyceryl trinitrate was used IV, as a uterine relaxant , to aid breech extraction (Greenspom), and to assist in replacing an inverted uterus and incases of removal of adherent placenta. Nitric oxide by increasing Cyclic GMP and cause myometrial relaxation . It can cause cardiovascular side effects like tachy cardia and hypotension. There are reports of use of nitric oxide donors suggest that they are effective

tocolytics in comparison with placebo delaying delivery for 48 hrs (smith etal, 1999) . Study by Afifa etal (2006), showed that glyceryl trinitrate can be used as safer tocolytic agent.

MATERIALS AND METHODS

Study on tocolysis in preterm labour was conducted in Government Rajaji Hospital from December 2010 to November 2011. 100 women with preterm labour randomly selected from the pregnant women attending antenatal OP and from labour ward from the department of obstetrics and gynecology, Government Rajaji Hospital , Madurai . Out of which 50 women were recruited for oral nifedipine and another 50 women were recruited for transdermal nitroglycerin patch.

The patients recruited for this study fulfilled the following inclusion criteria.

Inclusion criteria :

1) Singleton pregnancy with Gestational age from 28 weeks to 36 weeks
2) Regular painful uterine contractions minimum of two , every ten minutes and for more than 1 hour.
3) With intact membranes
4) cervical dilatation less than 1cm to 3 cm
5) No medical condition obviating medical therapy

If the following conditions are present, those patients were excluded from the study.

Exclusion criteria:

1) Premature rupture of membranes
2) Fetal distress
3) Major fetal congenital anomalies
4) Chorioamnionitis
5) Antepartum hemorrhage
6) Sensitivity or contra indication to nifedipine/nitrates.

All women meeting the eligibility criteria, were properly informed about the aims of the study and those who agreed to participates signed a consent form. Those women who were dignosed to have preterm labour were admitted in labour ward in the observational areas, where continuous monitoring was possible. A detailed history was obtained, under aseptic precautions, general , systemic , speclum and pervaginal examinations were done . Base line pulse, blood pressure and fetal heart rate were recorded . The findings were recorded on a predesigned proforma. Investigations like Blood hemoglobin, blood grouping and Rh typing, urine – albumin, sugar, blood sugar , urea, serum creatinine and ultrasonography were done. Two doses of betamethasone (12mg IM 24 hours apart) were administrated to all cases . Prophylatic antibiotics were also given for further prevention of infection.

50 patients were randomly selected for oral nifedipine and were designated as group I and the other 50 patients were selected for transdermal nitroglycerin patch and were designated as group II and time needed for tocolysis and prolongation of pregnancy and the neonatal outcomes were observed. The results are tabulated in performed proforma and meticulously analysed.

ORAL NIFEDIPINE (Group – I)

For women randomised to oral nifedipine, initially administered 20mg of nifedipine in the form of 10mg tablets x 2 tablets , and 10mg repeated after 30minutes if there is contractions. Then 10mg oral infedipine repeated every six hours, till the contractions stop.

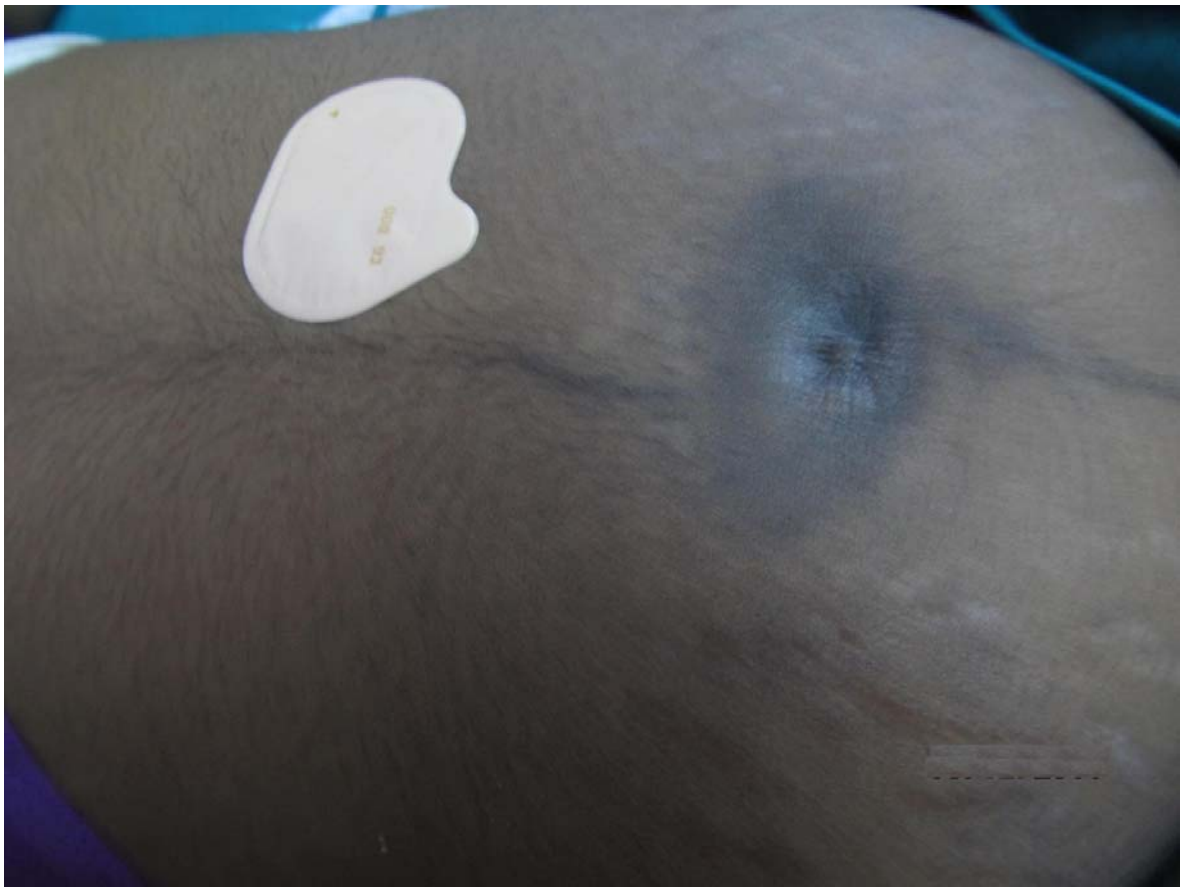
Monitoring :

Maternal pulse rate , blood pressure , fetal heart rate and uterine contractions were monitored initially every 15 minutes for first two hours. Then every two hours for 6 hours and every 6 hours for 48 hours.

Treatment was discontinued, if therewas :

1) Fall of Bp less than 90/60mmhg (or)
2) If the pulse rate is more than 100/mt (or)
3) If the patient had premature rupture of membranes (or)
4) If there was persistent uterine contractions even after 48 hours.

TRANSDERMAL NITROGLYCERIN PATCH APPLIED OVER THE ABDOMEN



5) If signs of fetal distress.

Side effects like dizziness, nausea noted in few patients.

The treatment was considered successful if uterine contractions subsided and tocolysis was achieved for more than 48 hours. This minimum time interval was chosen, because it was considered sufficient for the action of the administered steroids to decrease respiratory complications in premature neonate and for transfer to well equipped centre for further management of preterm neonate.

After contractions stopped, till 37 weeks of gestation patient was reviewed weekly once (or) follow up done, till delivery – if delivered before 37 weeks.

TRANSDERMAL NITROGLYCERIN PATCH (GROUP –II)

Women in preterm labour recruited for transdermal nitoglycerin study , transdermal nitroglycerin patch (25mg) (TTS -5) was directly applied to the skin of abdomen.

MONITORING :

Throughout, maternal pulse , blood pressure fetal heart rate were monitored every 15mts and occurence of uterine contractions also monitored every 15mts in the first two hours. Then, two hourly for 6 hrs followed by 6^{th} hourly for 48 hours.

Treatment was discontinued if

1. patient complaining of any headache ,
2. Hypotension less than 90/60mmhg ,
3. Pulserate more than 100/mt ,
4. If the patient had premature rupture of membranes
5. If there was persistent uterine contractions even after 48 hours.
6. If signs of fetal distress.

After contractions stopped, patient was reviewed every week upto 37 weeks of gestation . Otherwise till delivery if it occurs less than 37 weeks.

The results of the study is tabulated and analysed meticulously

STATISTICAL TOOLS

The information collected regarding all the selected cases were recorded in a Master Chart. Data analysis was done with the help of computer using **Epidemiological Information Package (EPI 2010)** developed by Centre for Disease Control, Atlanta.

Using this software range, frequencies, percentages, means, standard deviations, chi square and 'p' values were calculated. Kruskul Wallis chi-square test was used to test the significance of difference between quantitative variables and Yate's chi square test for qualitative variables. A 'p' value less than 0.05 is taken to denote significant relationship.


TAB. NIFEDIPINE (10mg)

DRUG PHARMACOLOGY

NIFEDIPINE :

Influx of calcium ions play an important role in uterine contractions . The production of uterine contraction requires an increase in myometrial intracellular calcium concentration. Calcium will bind to calmodulin and Calcium - calmodulin complex bind with enzyme myosin light chain kinase and phosphorylate the short chain of myosin and by production of ATP causes muscle contraction. The activity of myosin light chain kinase is central to the process of muscle contraction. Nifedipine has prominent smooth muscle relaxant property. It is the prototype Dihydropyridine (lipophilic) group of calcium channel blockers. Dihydropyridine are most potent calcium channel blockers. It acts on voltage sensitive L – type (Long lasting current) channels in uterine musculature and there by decrease the intracellular availability of calcium ion and cause uterine relaxation.

Nifedipine has rapid onset and short duration of action .

DOSAGE :

Available as 5mg , 10mg, also as 10mg, 20mg, sustained released tablets.


TRANSDERMAL NITROGLYCERIN
PATCH
Nitroderm TTS® 5
nitroglyc.
NOVARTIS
EXP 02.2014 LOT S0314 MFD 03.2011

PHARMACOKINETICS :

BIOAVAILABILITY :

It is about 30 – 60% , because of high first pass metabolism and with marked inter and intra individual variation . Peak occurs at 1 – 3 hours.

DISTRIBUTION :

It bound to plasma proteins and have extensive tissue distribution.

METABOLISM :

Nifedipine is metabolised in liver and excreted in urine.

ELIMINATION:

Elimination t½ of nifedipine is ranging from 2-6 hours.

GLYCERYL TRINITRATE :

Nitric Oxide is basically responsible for relaxation of smooth muscles of myometrium. This is brought about by formation of Nitric oxide – CGMP from L-arginine. In the early pregnancy, due to decreased excretion of nitrite and CGMP, plasma levels increases thereby indicating enhanced formation of nitric oxide . The myometrial concentration of Nitric oxide increases significantly, but in late pregnancy there is reduction of nitric oxide in myometrium and decidua. There fore contractile status increases towards term. Conrad et al localised nitric oxide in syncytio trophoblast of human placenta.

COMPOSITION :

Transdermal therapeutic system (TTS) containing 25mg (TTS – 5) 50mg (TTS-10) and 75mg (TTS-15) nitro glycerin are available for use.

PROPERTIES :

TTS is a flat multilayer system designed to delvier nitro glycerine continuously through a release membrane. TTS -5 denotes the nominal amount of nitro glycerine in mg delivered by the system per 24 hours. The nitro glycerine content will be 25mg and the rate of drug release per hour is 0.4mg.

ABSORPTION :

Following single application of nitroderm TTS, placental concentration of nitro glycerine reach a plateau within 2 hours. The plateau is maintained over the recommended period of application.

DISTRIBUTION :

The same plasma levels are obtained regardless of the site of application of the patch and the distribution of the drug is equal.

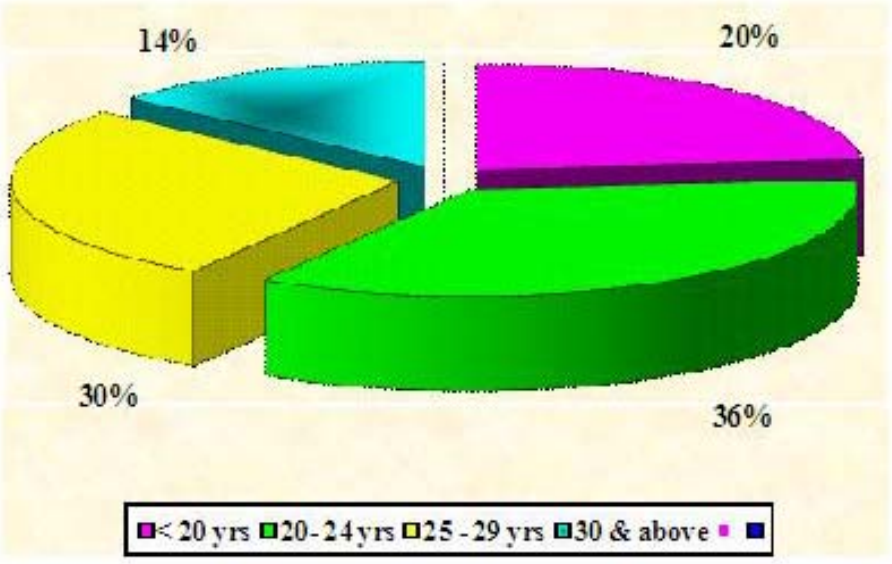
METABOLISM :

Transdermal glyceryl trinitrate is rapidly metabolised by glutathione dependent organic nitrate reductase in liver and excreted in urine.

ELIMINATION :

Plasma concentration drop below the level of detection within 1 hour after removal.

Age distribution



RESULTS AND ANALYSIS

The study was designed with a total sample of randomly selected 100 women who were in preterm labour out of which 50 women in randomly allotted for oral nifedipine in group I and another 50 women were randomly selected for Transdermal nitroglycerin patch in group II. All preterm labour women on study were given corticosteroids and prophylactic antibiotics. After inspection of the collected data from our study, the following results were observed .

Base line characteristics of the two groups were comparable.

Group I : Pregnant women with preterm labour given oral nifedipine (50 cases)

Group II : Pregnant women with preterm labour given transdermal nitroglycerin (50 cases).

A : PROFILE OF CASES STUDIED

Table 1

Age distribution

Age group	Group I		Group II	
	No	%	No	%
< 20 years	12	24	8	16
20 – 24 years	17	34	19	38
25 – 29 years	14	28	16	32
30 years and above	7	14	7	14
Total	50	100	50	100

Range	18- 35 years	18-32 years
Mean	23.9 years	24.0 years
SD	4.7 years	4.1 years
'p'	0.7165 Not significant	

The age distribution of the two groups has no significant difference. ('p' = 0.7165 Not Significant). The Maximum number of patients in both groups fall in age group between 20-24 years, 34% (17 out of 50) in group I and 38% (19 out of 50) in group II. 24% (12 out of 50) were teenagers in group I, when compared to group II it was 16% (8 out of 50). In both the groups 14% (7 out of 50) were more than 30 years of age. The mean age group in the study subject was 23.9 years in group I and 24 years in group II.

ANTE NATAL CARE

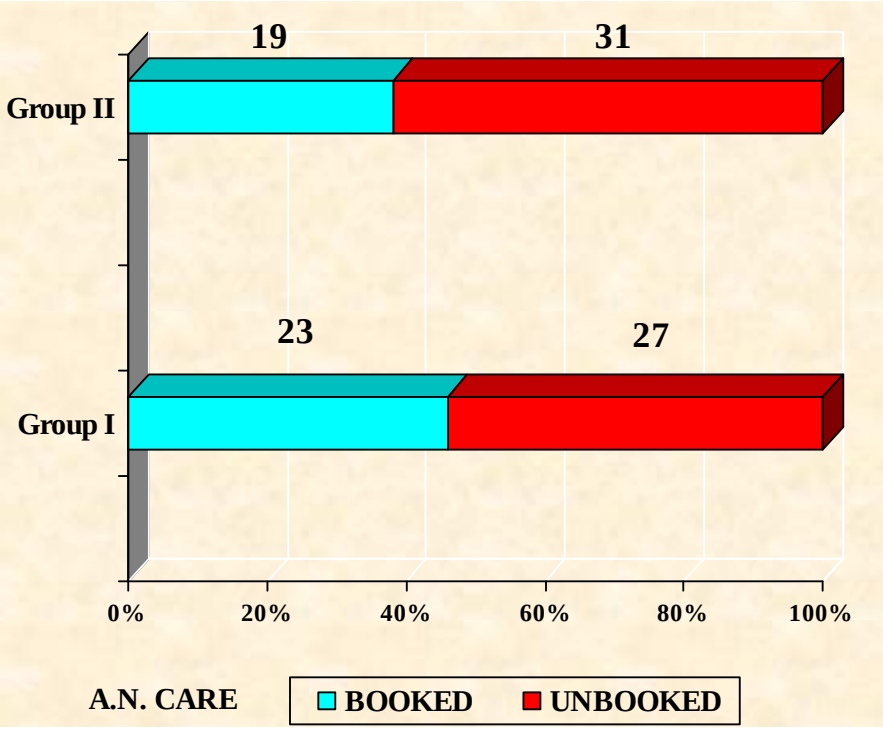


Table 2

Antenatal care

Age group	Group I		Group II	
	No	%	**No**	%
Booked	23	46	19	38
Unbooked	27	54	31	62
Total	50	100	50	100
'p'	0.5433 Not significant			

There is no significant difference in the Antenatal care received by the 2 groups of patients. (P Value = 0.5433 Not significant) 46% (23 out of 50) belonged to booked and 54% (27 out of 50) belonged to Unbooked in group I, Whereas 38% (19 out of 50) belonged to booked and 62% (31 out of 50) belonged to Unbooked in group II.

GRAVIDA

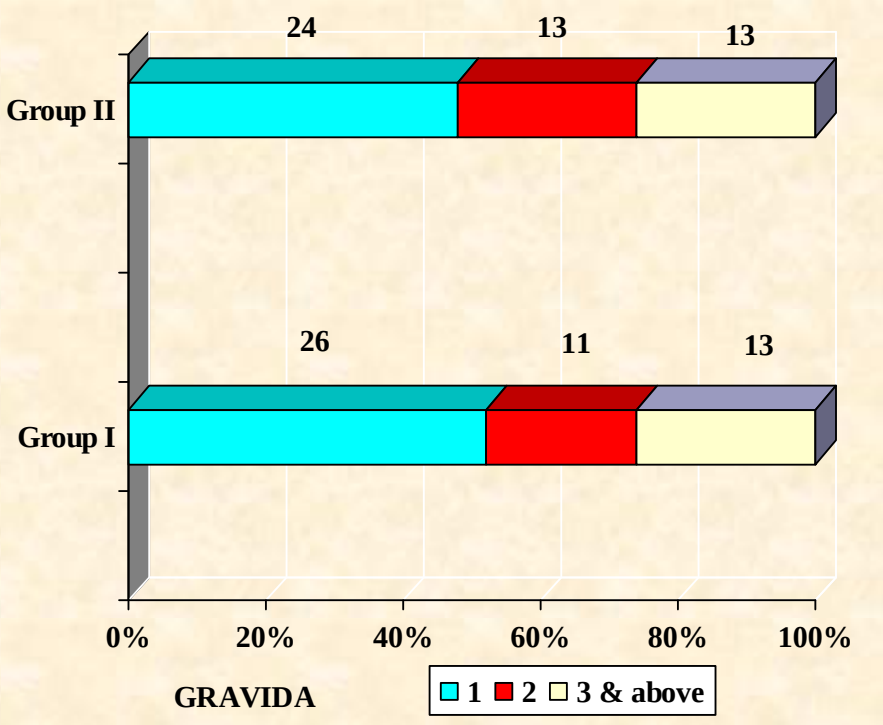

24
13
13
Group II
26
11
13
Group I
0%
20%
40%
60%
80%
100%
GRAVIDA
1
2
3 & above

Table 3

Parity

Gravida	Group I		Group II	
	No	%	No	%
Primigravida	26	52	24	48
2	11	22	13	26
3 and above	13	26	13	26
'p'	0.8961 Not significant			

There is no significant difference in the parity in both group I and group II (P value = 0.8961 Not significant). Primigravida comprised of about 52% (26 out of 50) in group I and 48% (24 out of 50) in group II Multiparous women in pre-term labour comprised of about 48% (24 out of 50) in group I and 52% (26 out of 50) in group II. Parity distribution was almost equal in both groups.

HISTORY OF PRE TERM LABOUR / PREVIOUS ABORTION

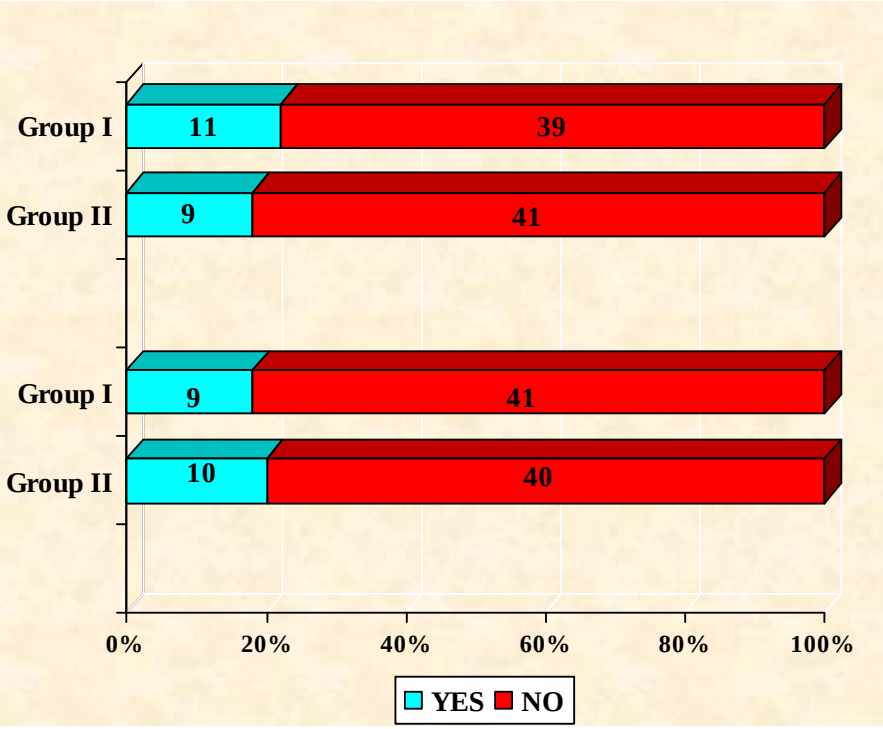


Table 4

History of preterm labour / abortion

History of	Group I		Group II	
	No	%	No	%
Preterm labour				
Yes	11	22	9	18
No	39	78	41	82
'p'	0.8026 Not significant			
Abortion				
Yes	9	18	10	20
No	41	82	40	80
'p'	0.8126 Not significant			

Pre-term labour in previous pregnancy was 22% (11out of 50) in group I and 18% (9 out of 50) in group II. There is no significant difference in the history of pre-term labour between the 2 groups of patients. (p=value 0.8126). History of previous abortion present in 18% (9 out of 50) in group I and 20% (10 out of 50) in group II patients. There is no significant difference in both the group of patients.

Table 5 : Gestational age on admission and mean prolongation

Gestational Age (in weeks)	No.of cases				Prolongation (Mean) (In days)	
	Group I		Group II		Group I	GroupII
	No	%	No	%		
28 – 30	9	18	6	12	32.8	21.8
31-32	19	38	16	32	24.8	14.8
33-34	17	34	21	42	14.0	13.8
35-36	5	10	7	14	4.8	7.7
Total	50	100	50	100	20.74	14.1

Though there was not much significant difference in the gestational age on admission in both groups, the time of prolongation of pregnancy varied considerably in both groups.

38% (19 out of 50) of group I study subjects were in 31-32 weeks of gestation and 32% (16 out of 50) in group II study subjects were in 31-32 weeks of gestation. 10% in group I were in more than 34 weeks, and 14% in group II were in more than 34 weeks. Mean prolongation in group I was 20.74 days. In group II, it was 14.1 days.

Mean duration of prolongation of pregnancy varied with gestational age on admission considerably both in group I and group II. When the gestational age was less than 30 weeks, the mean prolongation was 32.8 days in group I and it was 21.8 days in group II. When gestational age was between 31 – 32 weeks, the mean prolongation was 24.8 in group I where as in group II it was 14.8 days. When gestational age was between 33 and 34 weeks, mean prolongation in group I was 14 days and in group II it was 13.8 days. When the gestational age between 35 – 36 weeks prolongation 4.8 days in group I and 7.7 days in group II.

Table 6

Presentation

Presentation	Group I		Group II	
	No	%	No	%
Head	46	92	45	90
Breech	4	8	5	10
'p'	0.5 Not significant			

The distribution of the presenting part in both groups were equal. Majority of the patients in both groups had cephalic presentation 92% (46 out of 50) in group I and 90% (45 out of 50) in group II.

Table 7 : Cervical effacement

Cervical effacement	No.of cases				Prolongation (Mean) (In days)		'p'
	Group I		Group II		Group I	Group II	
	No	%	No	%			
25%	18	36	21	42	33.5	22.1	**0.003 Significant**
50%	19	38	14	28	20.6	13.1	0.0518 Not Significant
75%	13	26	15	30	3.3	2.8	0.3388 Not significant

Cervical effacement in both the groups had no significant difference . 36% (18 out of 50) in group I had 25% effacement and 42% (21 out of 50) in group II had 25% effacement. 38% (19 out of 50) in group I and 28% (14 out of 50) in group II had 50% effacement. 26% (13 out of 50) in group I and 30% (15 out of 50) had 75% effacement.

Cervical effacement considerably influenced on the mean prolongation of pregnancy, after tocolysis in both groups. Group I has mean prolongation of pregnancy significantly when compared to group II when the cervical effacement was 25%. (p = 0.003 signficant).

Table 8 : Cervical dilation

Cervical dilation (in cms)	No.of cases				Prolongation (Mean) (In days)		'p'
	Group I		Group II		Group I	Group II	
	No	%	No	%			
< 1	14	28	18	36	33.2	21.7	**0.0044 Significant**
1	17	34	16	32	25.4	15.1	**0.0128 Significant**
2	10	20	8	16	11.0	4.0	0.2431 Not significant
3	9	18	8	16	3.2	2.8	**0.645 Significant**

In mean prolongation of pregnancy, group I was having 33.2 days whereas in group II, it was 21.7 days (p = 0.0044 significant), when the cervical dilatation less than 1 cm. Mean prolongation with group I was 25.4 days and 15.1 days in group II (p = 0.0128 significant), when the cervical dilatation was 1 cm. With 2 cm dilatation of cervix, mean prolongation was 11 days in group I and 4 days in group II. When the

cervical dilation was 3 cms, mean prolongation with group I was 3.2 days and with group II was 2.8 days (p = 0.0458 significant).

Mean prolongation with group I was significant when compared to group II, in case of cervical dilatation 1cm or less than 1 cm.

Table 9 : Station of presenting part

Station of presenting part	No. of cases				Prolongation (Mean) (In days)		'p'
	Group I		Group II		Group I	Group II	
	No	%	No	%			
-3	20	40	12	24	29.2	15.25	**0.0011 Significant**
-2	21	42	29	58	20.43	15.54	0.4982 Not significant
-1	9	18	9	18	2.67	1.13	0.4138 Not significant

There is no significant difference in the distribution of station of presenting part in both the groups. In both groups 18% (9 out of 50) had presenting part at -1 station, and 82% (41 out of 50) in both the groups had the presenting part at and above -2 station. Mean prolongation of pregnancy was 29.2 days in group I and 15.25 days in group II (p = 0.0011 significant). When the station was -2, mean prolongation with group I was 20.4 days with group II was 15.5 days. Mean prolongation was 2.6 days in group I and 1.1 day in group II when the presenting part was at -1 station.

B : EFFICACY OF THE TWO DRUGS

Table 10 : Bishop score

Bishop score	No.of cases				Prolongation (Mean) (In days)		'p'
	Group I		Group II		Group I	Group II	
	No	%	No	%			
Upto 4	37	74	36	72	26.9	17.9	**0.0023 Significant**
Above 4	13	26	14	28	3.3	2.5	0.1572 Not significant

About 74% (37 out of 50) in group I and about 72% (36 out of 50) had bishop score upto 4, here the mean prolongation with group I was 26.9 days and 17.9 days with group II (p = 0.0023 significant. When the bishop score was above 4, mean prolongation with group I was 3.3 days and with group II was 2.5 days (p = 0.1572 not significant).

TIME NEEDED FOR TACOLYSIS

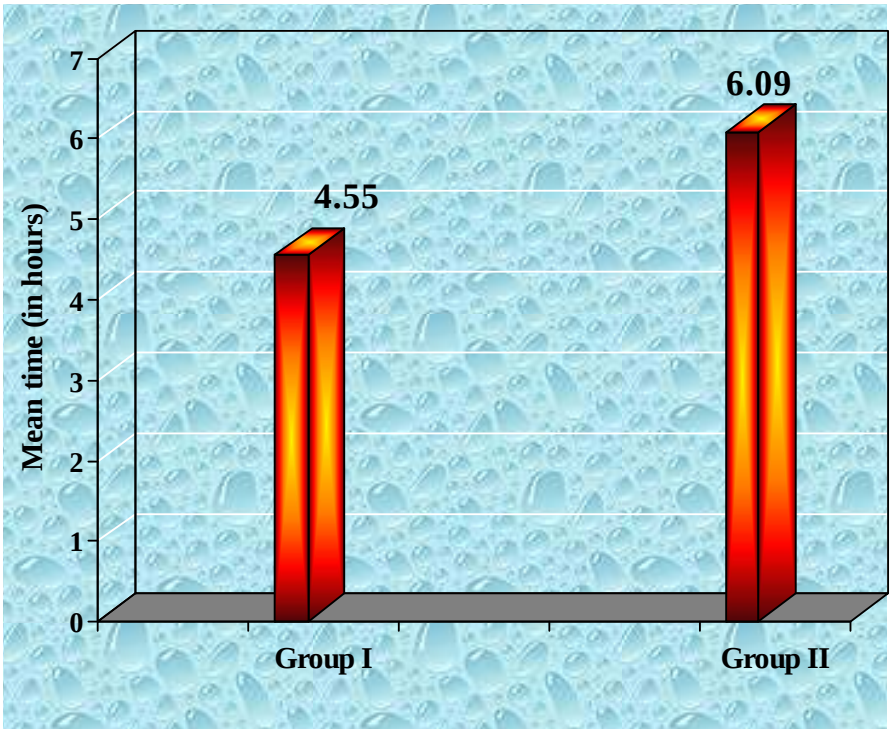


Table 11

Time needed for Tocolysis

Variable	Time needed for tocolysis	
	Group I	**Group II**
Range	2-12 hours	2-12 hours
Mean	4.55	6.09
SD	3.05	3.2
'p'	**0.006 Significant**	

Time needed for Tocolysis ranging between 2-12 hours in both the groups. Mean time needed for Tocolysis in group I was 4.55 hours and in group II it was 6.09 hours. 'P' Value = 0.006, significant

COMPLICATIONS

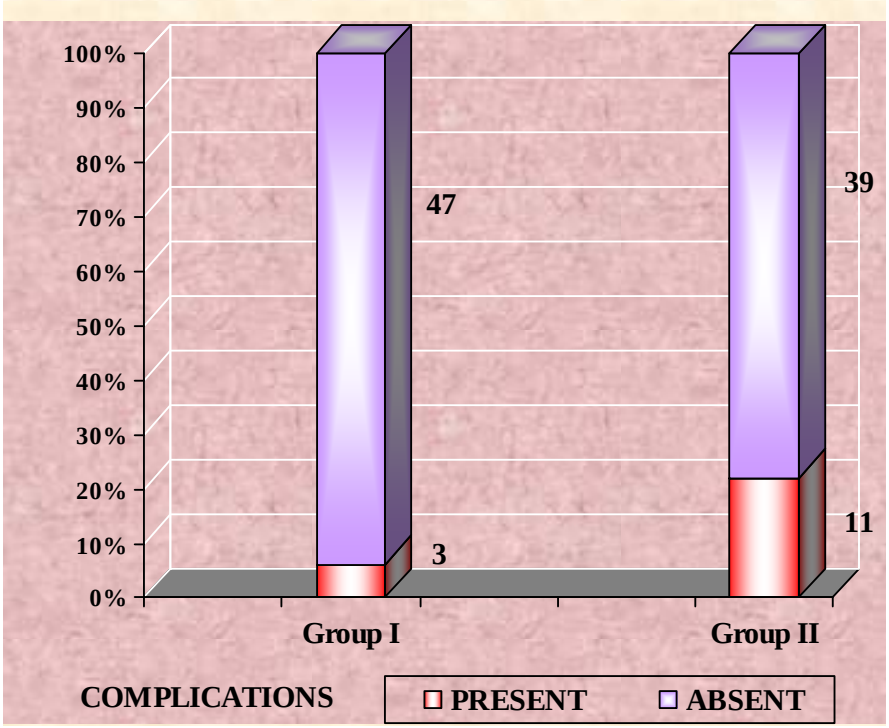


Table 12

Complications

Complications	Group I		Group II	
	No	%	No	%
Dizziness	1	2	2	4
Nausea	2	4	-	-
Tachycardia	-	-	2	4
Headache	-	-	7	14
'p'	**0.0437** **Significant**			

There is significant difference in the incidence of complications among the 2 groups of patients p(0.0437). Among group I, it was about 6% (3 out of 50) and in group II 22% (11 out of 50). Side effect with nifedipine was dizziness, Nausea. Headache was the main side effect seen with nitroglycerin No major systemic complications were faced in group I.

Table 13 : Gestational age at delivery

Gestational age at delivery (in weeks)	Group I		Group II	
	No	%	No	%
28-30	1	2	2	4
30-32	1	2	2	4
32-34	6	12	8	16
34-37	29	58	30	60
>37	13	26	8	16
Mean	35.49 weeks		34.89 weeks	
P	0.1563 Not significant			

When the gestational age at delivery was compared in both groups, it differed significantly. 4% (2 out of 50) were delivered in less than 32 weeks in group I, whereas 8% (4 out of 50) were delivered in less than 32 weeks in group II. In group I 26% (13 out of 50) were delivered after 37 weeks, it was 16% (8 out of 50) in group II. Mean gestational age at delivery in group I was 35.49 weeks, whereas in group II it was 34.89 weeks.

DURATION OF PROLONGATION

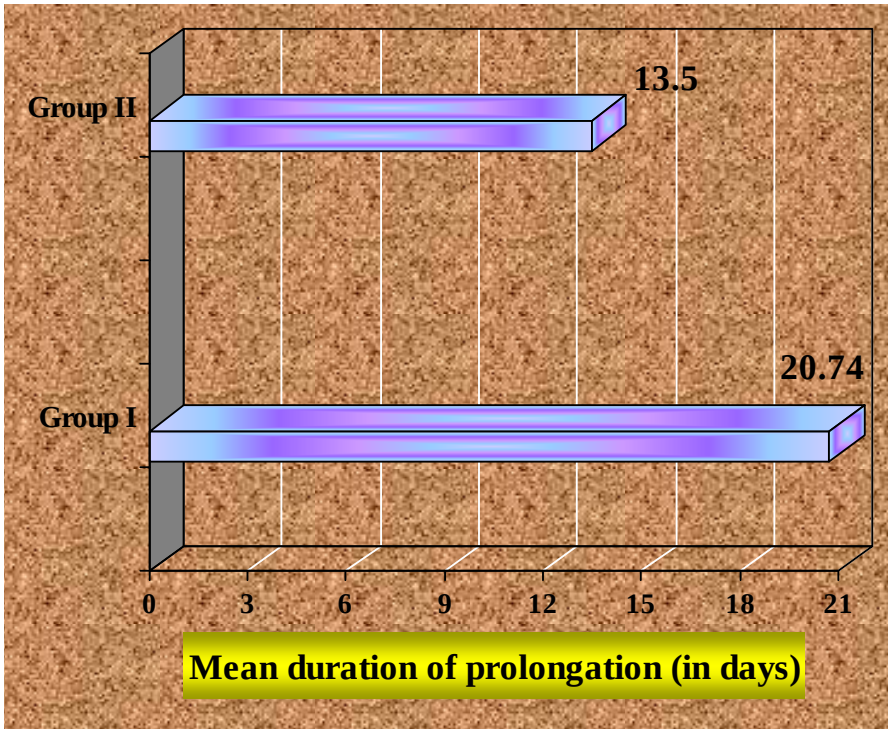


Table 14 : Duration of prolongation

Duration of prolongation	Group I		Group II	
	No	%	No	%
Same day	-	-	2	4
1 day	1	2	3	6
2 days	4	8	9	18
3 – 7 days	11	22	7	14
1 week – 2 weeks	3	6	9	18
2 – 4 weeks	15	30	16	32
> 4 weeks	16	32	4	8
Range	1-60		0-44	
Mean	20.74		13.5	
P	**0.0193 Significant**			

The treatment delivery interval differed significantly in both groups. About 4% (2 out of 50) delivered on the same day in group II. Where as no one had delivered on the same day in group I. 6% delivered in 1 -2 weeks in group I and 18% in group II. 22% (11 out of 50) in group I and 14%(7 out of 50) in group II delivered within 3 – 7 days. When delivery after 4 weeks was compared 32% (16 out of 50) in group I and 8% (4 out of 50) in group II, delivered after 4 weeks (p = 0.0059 significant).

ACUTE TOCOLYTIC EFFECT

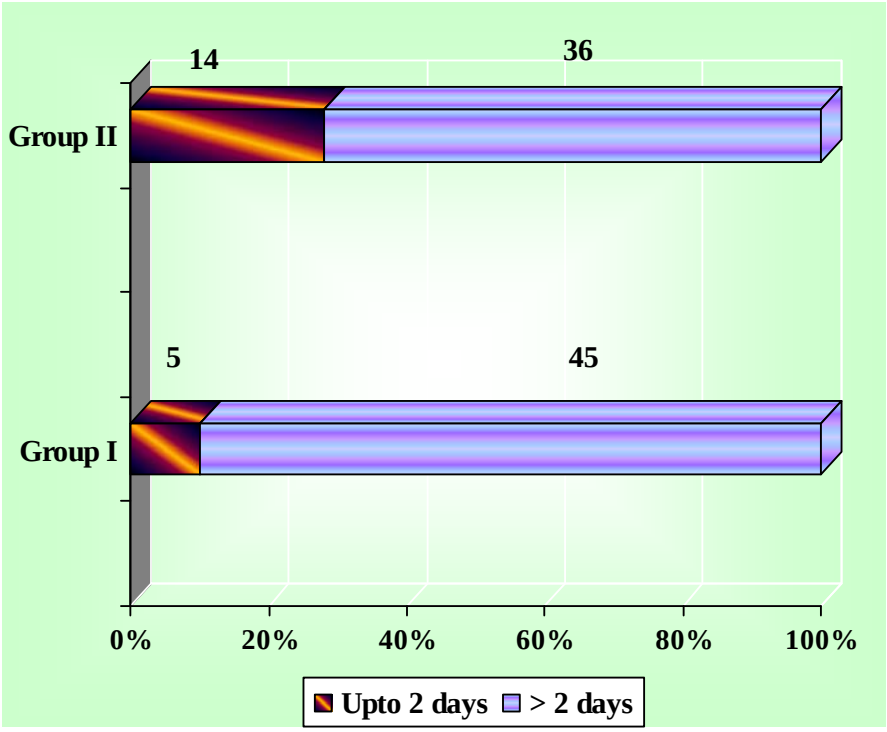


Table 15 : Acute tocolytic effect

Treatment delivery interval	Group I		Group II	
	No	%	No	%
Upto 2 days	5	10	14	28
> 2 days	45	90	36	72
Total	50	100	50	100
'p'	**0.0414 Significant**			

The acute tocolytic effect between the 2 groups was significantly different (p = 0.0414 significant). Only 10% (5 out of 50) in group I delivered within 2 days but in group II it was 28% (14 out of 50). 90% (45 out of 50) were crossed the period of 48 hours for effective action of steroids in group I. But in group II only 72% (36 out of 50) crossed the period of 48 hours.

Table 16

Birth weight

Birth weight	Group I		Group II	
	No	%	No	%
< 2.5 kgs	29	58	34	68
≥ 2.5 kgs	21	42	16	32
Mean	2.32 kgs		2.19 kgs	
'p'	0.1778 Not significant			

There is no much significant difference in the birth weight of the babies in both the groups. In group I mean birth weight was 2.32kg where as in group II mean birth weight was 2.19kg.

APGAR SCORE

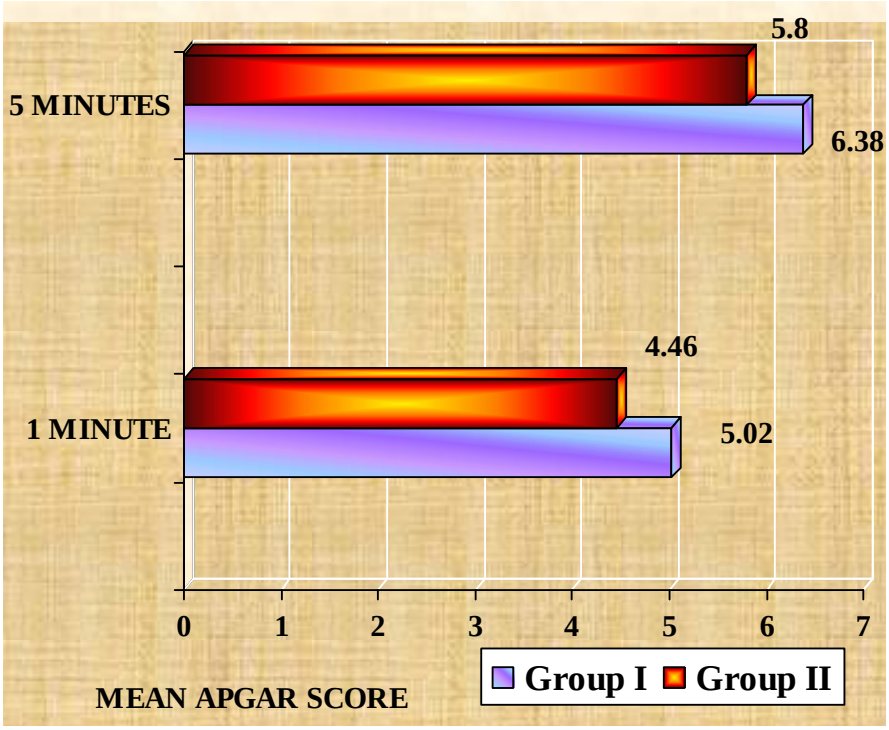

5.8
5 MINUTES
6.38
4.46
1 MINUTE
5.02
0
1
2
3
4
5
6
7
MEAN APGAR SCORE
Group I
Group II

Table 17

Apgar Score

Apgar score at	Group I		Group B		'p'
	Mean	**SD**	**Mean**	**SD**	
1 minute	5.02	0.96	4.46	1.09	**0.0072 Significant**
5 minutes	6.38	1.14	5.8	0.95	**0.0075 Significant**

Babies born in group I had mean apgar 5.02 and in group II mean apgar 4.46. in 1 minute 'p' value = 0.0072 (significant). 5 minute apgar was 6.38 in group I babies and it was 5.8 in group II babies 'p' value = 0.0075 (significant).

NEONATAL COMPLICATIONS

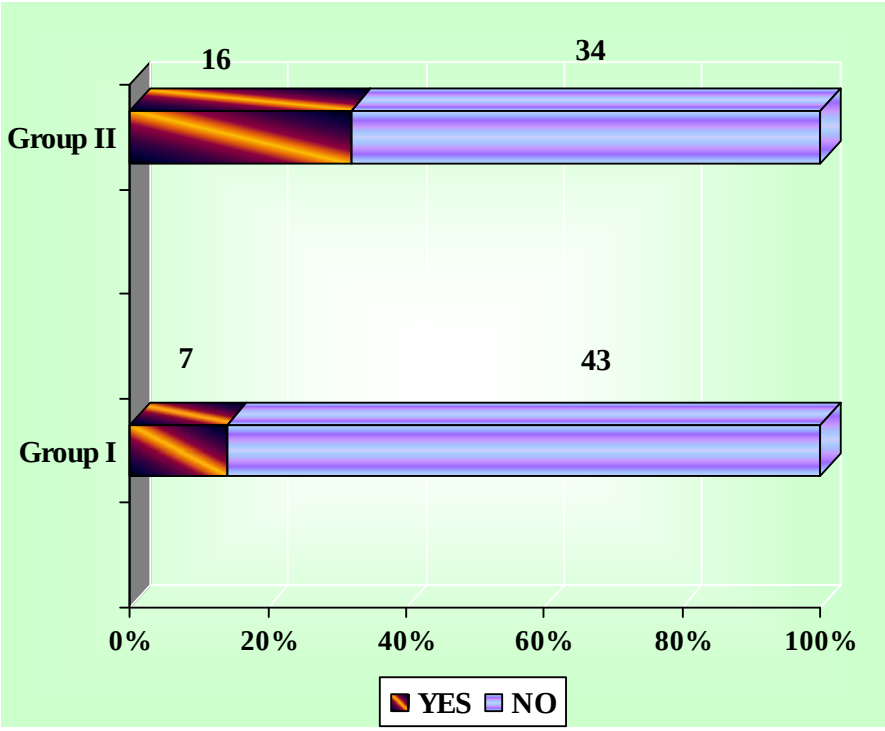


Table 18

Neonatal morbidity

Neonatal Morbidity (NICU admission)	Group I		Group II	
	No	%	No	%
Yes	7	14	16	32
No	43	86	34	68
'p'	**0.05 Significant**			

Admission in neonatal ward differed significantly. Only 7 Babies (14%) in group I got admitted in neonatal ward where as in group II 16 babies (32%) got admitted. This indicates, nifedipine successfully reducing the neonatal admission and had the better perinatal out come.

DISCUSSION

On analysing the outcome data, tocolysis with oral nifedipine is considered safe with good therapeutic efficacy compared to transdermal nitroglycerin patch.

When this data was compared with previous study, baseline characteristics did not differ significantly. In the study by Amorim et al (2009-11), Pregnant women aged between 18 and 40 yrs with singleton pregnancies. In our study, the patients in Group-I between 18 to 35 yrs and in Group-II between 18 to 32 years were recruited. Gestational age at inclusion was between 24 to 34 weeks, in Amorim study . Gestational age at entry differed considerably in each study group. In the study by Taherian (2007), it was 26-36 weeks. In Kashanian (2005) study, gestational age varied from 26-34 weeks. Gastational age between 26-36 weeks recruited in Ganla (1999) study. Papatsonis (1997) study included the 20-33 weeks gestational age. In the study by Smith GN (2007), gestational age between 24 to 32 weeks included. In afifa etal (2007) 28 weeks to 36 weeks were taken for study. In our study, the patients recruited had the gestational age from 28 to 36 weeks. Maximum number of

patients fell in the gestational age group of 31 to 34 weeks (74%) both in nifedipine and in nitroglycerin group.

Cervical dilatation in our study in the range of 3cm or less, where as in the study by Amorim (2009-11), cervical dilatation was 2-4cm and bag full of water. In Afifa (2007) study, cervical dilatation 0-4cm. In study by KOKs (1998), cervical dilatation was 2cm (or) less. Cervical dilatation influenced much on the prolongation of pregnancy when cervical dilatation exceeded more than 2cm, tocolytic efficacy was minimal. Mean prolongation of pregnancy with nifidipine in study by Agustin et al (2011) was 5.8 days. In Afifa study with nitroglycerin patch, mean prolongation was 2 days. In our study, when cervical dilatation was 3cm, mean prolongation of pregnancy with nifedipine was 3.2 days and with nitroglycerin was 2.8 days.

In study by Amorim (2009) nifedipine 10mg sublingually given, repeated after 30 minutes. Then 20mg orally every 6 hours for atleast 24 hours. In our study 20mg nifedipine given orally, followed by 10mg after 30 minutes and 10mg every 6 hours till the contractions stopped. In Amorim study (2009), Nitroglycerin

patch, used was 10mg, in our study nitroglycerin transdermal patch 25mg was used.

In study by Amorim (2009), no significant difference of frequency of side effects presented by patients, except for headache which was about 30%, who received nitroglycerin and 8.3% with nifedipine. In our study headache occurred in 11 patients (22%) who received nitroglycerin and dizziness (2%), Nausea (4%) in patients had oral nifedipine. Because of minimal side effects nifedipine is considered safer. Study by Agustin et al (2011) showed that nifedipine appeared to be effective tocolytic agent and had improvement in neonatal outcome.

The success rate of acute tocolysis was 87.5% with nifedipine and 84.6% with nitroglycerin in Amorim (2009) Study. In the study conducted here success rate of acute tocolysis with oral nifedipine was 90% and with nitroglycerin was 72%.

The time average needed for tocolysis was 5.8 hours with oral nifedipine and 6.6 hours with nitroglycerin. In our study time needed for tocolysis was 4.55 hours for oral nifedipine and 6.09 hours for transdermal nitroglycerin patch.

Mean prolongation of pregnancy upto more than 4 weeks with nifedipine was 32% and with nitroglycerin was 8% in our study.

Tocolytic efficacy of oral nifedipine was comparatively better than nitroglycerin, because of better acute tocolytic effect, reduced maternal complication, good neonatal outcome and lower preterm delivery rate and with good prolongation of pregnancy.

Safety, efficacy, acceptability limits the usage of a drug. Nifedipine is considered to be safer for its ease of use, metabolism and elimination of drug with minimal side effects. While efficacy was studied, nifedipine acts as a good tocolytic, for effective action of corticosteroids and to provide time for the patient to get transferred to tertiary neonatal care unit.

As a secondary analysis, an economic evaluation of the trial was done. Cost of oral nifedipine is less when compared to transdermal glyceryl trinitrate, which is costlier. Because all of these, good acute tocolytic efficacy, less maternal side effect good neonatal outcome, less cost, nifedipine was superior to glyceryl trinitrate. The rapid and effective action obtained with nifedipine,

its simplicity of administration and safety, suggest that nipedifine, makes major contribution to the management of preterm labour.

SUMMARY

This study was conducted in 100 patients with preterm labour who were randomly selected from the Department of Obstetrics and gynecology, those who attending the antenatal OP. They were divided into Group I (50) and Group II (50) randomly. Group I received oral nifedipine and Group II received transdermal nitroglycerin patch. The results were analysed and studied.

1. Age:

Age distribution between the two groups was found to be equal. Majority of the patients were belonged to age group of 20-29 years (31 patients in group I (62%) and 35 patients in group II (70%). In both the groups 14% (7 patients) were belonged to 30 years and above.

2. Antenatal Care:

Most of the patients in this study group were found to be unbooked (54% in group I and 62% in group II). 46% in group I and 38% in group II were found to be booked.

3. Parity:

Parity distribution was found to be equal in group I and group II. Half of them were found to be primigravida (52% in group I and 48% in group II.

4. History of Preterm labour / Abortion

Previous History of preterm labour was present only in minority of patients. (22% in Group I and 18% in group II). History of abortion also present in minority of patients. (In group I 18% and in group II 20%)

5. Gestational age on admission:

Majority of the patients in the study groups were found to be in the gestational age between 31 – 34 weeks.

6. Presentation:

92% in group I had cephalic presentation and 90% in group II had cephalic presentation. 8% in group I and 10% in group II had podalic presentation.

From the above analysis, this study group has equal distribution of cases both in group I and group II as far as age, parity, booking, presentation, gestational age on admission, previous history of abortion and preterm labour were concerned.

7. Cervical effacement at the time of treatment:

Both in group I and group II, about 1/4th of the patients (26% in group I and 30% in group II) had belonged to 75% effacement. 36% in group I and 42% in group II had 25% effacement and 38% in group I, 28% in group II had 50% effacement. The more the effacement lesser is the duration of prolongation of pregnancy both in group I and group II. Mean prolongation of pregnancy was 33.5 days in group I and 22.1 days in group II, when the effacement of 25%. 3.3 days prolonged in group I and 2.8 days prolonged in group II, when the effacement was 75%.

8. Cervical dilatation at the time of treatment:

18% in group I and 16% in group II had 3cm dilatation. 62% in group I and 68% in group II had cervical dilatation of 1cm and less than 1cm. When the cervical dilatation 3cm prolongation of

pregnancy less in both the groups. Mean prolongation of about 3.2 days with group I and about 2.8 days with Group II.

9. Station of presenting part:

There is no significant difference in the distribution of station of presenting part in both the groups. 82% patients in both groups had presenting part at and above- 2 stations. 18% of patients had presenting part at -1 station both in group I and Group II.

Duration of prolongation of pregnancy decreases, when the station of the presenting part comes down, in both groups. Mean prolongation with group I was 29.2 days and with Group II was 15.25 days when the station was above -2.

10. Bishop Score

About 74% in group I and 72% in group II had bishop score 4 or less than 4. Here the mean prolongation of pregnancy in group I was 26.9 days whereas in group II it was 17.9 days. When the bishop score more than 4, mean duration of prolongation was less.

11. Time needed for tocolysis:

Both in group I and group II – time needed for tocolysis ranged from 2 - 12 hours. Mean time needed for tocolysis in group I was 4.55 hours when compared with group II, it was 6.09 hours.

12. Complications:

Only 6% of patients in group I and 22% in group II had side effects. Dizziness (2%), nausea (4%) were found in group I where as headache (14%) was main side effect with group II. It shows, group I has minimal side effects and it is safer.

13. Gestational age at delivery:

About 26% in group I delivered after 37 weeks whereas in 16% in group II delivered after 37 weeks.

14. Duration of Prolongation:

In group I, 32% were delivered after 4 weeks, but in group II only 8% were delivered after 4 weeks. 4% in group II were delivered on the same day, but none in group I.

15. Acute tocolysis:

When acute tocolytic effect was compared (that is women who had prolongation of pregnancy more than 48 hours) it was 90%, in group I and 72% in group II.

16. Neonatal outcome and Neonatal morbidity:

When birth weight of babies, compared 58% in group I and 68% in group II had less than 2.5kg and 42% in group I, 32% in group II had birth weight more than 2.5kg. 1 minute mean apgar 5.02 in group I and 4.4 in group II, 5 minutes mean apgar was 6.38 in group I and 5.8 in group II. New born ward admissions were 32% in group II whereas in group I it was only 14%.

CONCLUSION

When compared with nitroglycerin, nifedipine is found to be absolutely safe and successful in achieving complete tocolysis.

Nifedipine is not only good in acute tocolysis but also very effective in prolonging the pregnancy more than 28 days, when in comparison with nitroglycerin.

When side effects are compared, nifedipine has minimal side effects. Neonatal outcome was good with nifedipine, because it had better apgar and less morbidity in neonates.

To conclude, oral nifedipine has a very good role to play in the treatment of acute tocolysis and for prolongation of pregnancy. So it can be considered as the first line drug of choice.

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PROFORMA

NAME : AGE : IPNO : UNIT:
ADDRESS : PARITY: BOOKED

/ UNBOOKED:

DOA :

MENSTRUAL HISTORY : REGULAR / IRREGULAR

LMP : GESTATIONAL AGE :

EDD :

HISTORY OF PRESENT ILLNESS:

H/O LABOUR PAIN

H/O DYSURIA

H/O STERNOUS WORK / STRESS

H/O FIRST TRIMESTER SPOTTING

H/O COITUS

H/O WHITE DISCHARGE]

PAST HISTORY

PRETERM LABOUR : YES / NO

DIABETES MELLITUS : YES / NO

HYPER TENSION : YES / NO

HEART DISEASE : YES / NO

BRONCHIAL ASTHMA : YES / NO

EPILEPSY : YES / NO

GENERAL EXAMINATION

FEBRILE : YES / NO PR :

ANEMIA : YES / NO BP :

PEDAL EDEMA : YES / NO RR :

CVS :

RS :

ABDOMINAL EXAMINATION

UTERUS SIZE IN WEEKS :

UTERINE CONTRACTIONS : NUMBER OF CONSTRACTION / DURATION OF CONSTRACTION

PRESENTING PART : HEAD / BREECH / OTHERS

FETAL HEART RATE :

VEGINAL EXAMINATION

CERVIX EFFACEMENT : 25% / 50% / 75%

DILATATION : 1F / 2F / 2CM / 3CM

MEMBRANES : PRESENT / ABSENT

PRESENTING PART : VERTEX / BREECH / OTHERS

STATION : -3 / -2 / -1 / 0

PELVIS : GYNAECOID / OTHER

PERVAGINAL : SHOW / DISCHARGE

BISHOP SCOPE :

INVESTIGATIONS

BLOOD

HB :

SUGAR :

UREA :

S.CREATININE :

URINE:

ALBUMIN :

SUGAR :

DEPOSITS :

ULTRASONOGRAM

SINGLETON / MULTIPLE :

VERTEX / BREECH / OTHERS :

GESTATIONAL AGE : 28-30WK/30-32WK / 32-34WK/34-36WK

PLAGENTA :

AFI :

CONGENITAL ANOMALIES :

EFW :

TREATMENT:

INJ. AMPCILLIN : 500 mg (IV / BD)

INJ. BETAMETHASONE : 12 mg / IM / 24 hrs APART

GROUP 1 NIFEDIPINE : LOADING DOSE 20 – 30 mg

MAINTENANCE DOSE 10 – 20 mg

TIME	**15min**	**30min**	**45min**	**1 hr**	**2 hrs**	**4 hrs**	**6 hrs**	**12 hrs**	**24 hrs**	**48 hrs**
CONTRACTION										
MPR										
MBP										
FHR										
DOSE										

GROUP 2 NITROGLYCERINE : 25 mg PATCH

TIME	15min	30min	45min	1 hr	2 hrs	4 hrs	6 hrs	12 hrs	24 hrs	48 hrs
CONTRACTION										
MPR										
MBP										
FHR										

SIDE EFFECTS : TACHYCARDIA / HYPOTENSION / HEADACHE

OUTCOME : DELIVERED / DISCHARED

ELIVERED

DATE OF DELIVERY :

MODE OF DELIVERY : LN / FORCEPS / LSCS

BABY DETAILS : WT : SEX : APGAR: 1 MIN 5 MIN

ADMISSION DELIVERY INTERVAL:

1 DAY 2DAYS 2-7 DAYS 1-2 WEEKS 2-3WEEKS 3-4 WEEKS >4 WEEKS

DELIVERY AT

28 -30 WEEKS 30-32 WEEKS 32-34WEEKS 34-36WEEKS >37 WEEKS

NEONATAL OUTCOME / MORBIDITY

MASTER CHART

GROUP - I

Sl.No	Age	IP.No	Date of admission	Booked unbooked	G	P	L	A	H/O Preterm Labour	Gestrational age	Presentation	Cervical effacement	Cervical dilatation	Station	Bishop score	Time needed for tocolysis	Complications	Date of delivery	Gestational age atdelivey (in weeks + days)	Duration of prolongation (in days)	Birth weight (kg)	1 minute	5 minutes	Neonatal morbidity
1	19	6725	02/07/2011	UB	1	0	0	0		32	HEAD	50%	1CM	-3	2	2.5hrs	NIL	15/3/11	37+ 3	38	2.5	6	8	Nil
2	32	6990	02/10/2011	UB	4	1	1	2		34	HEAD	25%	1CM	-3	1	2hrs	NIL	9/3/2011	37+ 6	27	2.7	6	8	Nil
3	24	7221	15/02/2011	B	1					35	HEAD	75%	3CM	-1	6	12hrs	NAUSEA	20/2/11	35+5	5	2.1	5	6	Nil
4	20	7411	22/02/2011	B	2			1		32	HEAD	50%	1CM	-3	3	2.5hrs	NIL	24/3/11	36+2	30	2.4	5	6	Nil
5	21	7456	22/02/2011	UB	1					32	BREECH	25%	<1CM	-3	2	2hrs	NIL	10/4/2011	38+5	47	2.6	6	7	Nil
6	20	8215	03/01/2011	B	1					35	HEAD	50%	1CM	-2	4	2.5hrs	NIL	11/3/2011	36+3	10	2.3	6	7	Nil
7	20	8819	03/04/2011	B	1					32	HEAD	25%	1CM	-3	1	2hrs	NIL	1/4/2011	35+2	23	2.6	5	7	Nil
8	27	8998	20/03/2011	UB	2	1	1		YES	34	HEAD	50%	2CM	-2	4	6hrs	NIL	10/4/2011	37	21	2.7	6	8	Nil
9	25	9202	25/03/2011	B	2	1	1			32	HEAD	25%	1CM	-3	2	2hrs	NIL	22/4/11	36	28	2.4	5	7	Nil
10	19	9314	28/03/2011	UB	1					30	HEAD	25%	1CM	-2	2	3hrs	NIL	27/5/11	38+4	60	2.8	6	8	Nil
11	21	9916	04/02/2011	B	1					28	BREECH	75%	2CM	-1	6	6hrs	NIL	5/4/2011	28+4	3	1.25	2	4	Admission
12	35	10134	04/07/2011	UB	3	2	2		YES	35	HEAD	75%	3CM	-2	6	6hrs	NIL	10/4/2011	35+3	3	2.4	5	6	Nil
13	26	10358	04/12/2011	B	3	1	1	1		30	HEAD	25%	<1CM	-2	2	2hrs	NIL	23/5/11	35+6	41	2.6	5	6	Nil
14	24	10755	20/04/2011	B	1					34	HEAD	50%	1CM	-2	3	4hrs	NIL	15/5/11	37+4	25	2.8	6	7	Nil
15	18	10932	24/04/2011	UB	1					32	HEAD	50%	1CM	-3	2	3hrs	NIL	6/6/2011	38+1	43	2.7	6	8	Nil
16	21	11004	29/04/2011	UB	1					34	HEAD	25%	<1CM	-3	2	2hrs	NIL	22/5/11	37+2	23	2.6	6	7	Nil
17	24	11138	05/05/2011	UB	2	1	1			34	HEAD	75%	3CM	-2	6	8hrs	NAUSEA	8/5/2011	34+3	3	2.2	5	6	Nil
18	19	11483	14/05/2011	B	1					34	HEAD	50%	2CM	-3	3	2hrs	NIL	31/5/11	36+3	17	2.4	5	6	Nil
19	21	11870	22/05/2011	B	1					30	HEAD	50%	2CM	-2	3	2hrs	NIL	26/6/11	35	35	2.3	5	6	Nil
20	33	11994	28/05/2011	UB	4	2	2	1		32	HEAD	50%	2CM	-2	3	4hrs	NIL	14/6/11	34+3	17	2.1	4	6	Nil
21	19	12125	06/02/2011	B	1					28	BREECH	25%	<1CM	-2	2	2hrs	NIL	14/7/2011	34	42	2	5	6	Nil
22	31	12248	06/05/2011	UB	2	1	1			32	HEAD	50%	1CM	-2	3	3hrs	NIL	28/6/11	35+2	23	2.3	5	6	Nil
23	32	12433	06/09/2011	UB	3	2	2		YES	34	HEAD	75%	3CM	-1	6	8hrs	NIL	13/6/11	34+4	4	2.2	4	6	Nil
24	28	12512	06/11/2011	UB	2	1	1		YES	34	HEAD	75%	3CM	-1	6	6hrs	NIL	13/6/11	34+2	2	2	5	6	Nil
25	24	12702	14/06/2011	B	2	1	1			30	HEAD	25%	<1CM	-3	1	2hrs	NIL	26/7/11	36	42	2.6	6	7	Nil

26	18	12818	18/06/2011	UB	1					32	HEAD	75%	3CM	-2	5	8hrs	NIL	24/6/11	32+6	6	1.5	3	4	Admission
27	22	12976	23/06/2011	B	1					30	HEAD	50%	1CM	-3	3	3hrs	NIL	24/7/11	34+3	31	2.3	5	6	Nil
28	27	13028	27/06/2011	UB	4	2	1	1	YES	32	HEAD	75%	2CM	-2	5	6hrs	NIL	3/7/2011	32+6	6	1.8	4	5	Admission
29	23	13159	07/01/2011	B	1					34	HEAD	25%	<1CM	-3	2	2hrs	NIL	15/7/11	36	14	2.4	5	6	Nil
30	25	13210	07/03/2011	UB	2	1	1		YES	28	BREECH	25%	<1CM	-2	2	2.5hrs	NIL	17/8/11	34+3	45	2.2	5	6	Nil
31	28	13293	07/05/2011	B	3	1	1	1		32	HEAD	75%	3CM	-1	6	8hrs	DIZZINESS	7/7/2011	32+2	2	1.7	4	5	Admission
32	27	13457	07/09/2011	UB	3	1	1	1		34	HEAD	50%	1CM	-3	3	4hrs	NIL	1/8/2011	37+2	23	2.9	6	8	Nil
33	29	13604	07/12/2011	B	4	3	2			30	HEAD	50%	2CM	-1	4	6hrs	NIL	15/7/11	30+3	3	1.4	3	4	Admission
34	18	13836	15/07/2011	B	1					32	HEAD	25%	<1CM	-3	1	2hrs	NIL	22/8/11	37+3	38	3	6	8	Nil
35	19	13999	18/07/2011	B	1					34	HEAD	50%	1CM	-3	3	4hrs	NIL	4/8/2011	36+3	17	2.5	5	6	Nil
36	21	14188	20/07/2011	B	1					32	HEAD	25%	<1CM	-3	1	2.5hrs	NIL	31/8/11	38	42	3	6	8	Nil
37	28	14514	24/07/2011	UB	2	1	1			34	HEAD	50%	1CM	-3	2	2hrs	NIL	15/8/11	37+1	22	2.9	6	8	Nil
38	30	14980	28/07/2011	UB	3	2	2		YES	32	HEAD	50%	2CM	-2	4	6hrs	NIL	31/7/11	32+3	3	1.6	4	5	Admission
39	19	15012	29/07/2011	UB	1					32	HEAD	25%	<1CM	-2	2	2hrs	NIL	29/8/11	36+3	31	2.4	5	6	Nil
40	18	15278	08/02/2011	B	1					34	HEAD	50%	1CM	-3	2	2hrs	NIL	21/8/11	36+5	19	2.7	6	7	Nil
41	34	15312	08/05/2011	UB	4	3	2		YES	36	HEAD	75%	2CM	-1	6	8hrs	NIL	6/8/2011	36+1	1	2.5	5	6	Nil
42	27	15635	08/10/2011	B	1					32	HEAD	75%	3CM	-1	7	10hrs	NIL	12/8/2011	32+2	2	1.3	3	4	Admission
43	25	15923	16/08/2011	UB	1					32	HEAD	25%	<1CM	-3	1	2hrs	NIL	21/9/11	37+1	36	2.7	6	8	Nil
44	19	16298	23/08/2011	UB	1					34	HEAD	25%	<1CM	-2	2	2.5hrs	NIL	7/9/2011	36+1	15	2.6	5	7	Nil
45	22	16902	09/02/2011	B	3	1	1	1	YES	34	HEAD	50%	1CM	-2	3	4hrs	NIL	7/9/2011	34+5	5	2.2	5	6	Nil
46	19	17120	09/07/2011	UB	1					32	HEAD	25%	<1CM	-3	1	2hrs	NIL	1/10/2011	35+3	24	2.4	5	6	Nil
47	26	17805	15/09/2011	UB	2	1	1		YES	36	HEAD	75%	2CM	-2	6	12hrs	NIL	19/9/11	36+4	4	2.4	5	7	Nil
48	21	17998	22/09/2011	UB	3	1	1	1	YES	34	HEAD	75%	3CM	-1	6	12hrs	NIL	24/9/11	34+2	2	1.9	5	6	Nil
49	25	18148	25/09/2011	B	2	1	1			34	HEAD	50%	1CM	-2	3	4hrs	NIL	4/10/2011	35+2	9	2.2	5	6	Nil
50	25	18329	10/01/2011	UB	1					32	HEAD	25%	<1CM	-2	2	2hrs	NIL	2/11/2011	36+4	32	2.5	6	7	Nil

GROUP - II																								
51	27	6825	02/09/2011	UB	2			1		34	HEAD	50%	2CM	-2	4	6hrs	NIL	15/2/11	34+6	6	2.2	5	6	Nil
52	21	7175	02/12/2011	B	1					31	HEAD	25%	<1CM	-1	3	4hrs	NIL	28/3/11	37+2	44	2.7	6	7	Nil
53	25	7318	18/02/2011	B	2	1	1			34	HEAD	25%	<1CM	-3	1	2hrs	NIL	4/3/2011	36	14	2.3	6	7	Nil
54	21	7367	18/02/2011	UB	1					34	HEAD	25%	<1CM	-2	2	4hrs	NIL	13/3/11	37+2	23	2.6	5	6	Nil
55	28	7814	25/02/2011	UB	3	1	1	1		34	HEAD	25%	1CM	-2	2	3hrs	NIL	9/3/2011	35+5	12	2.4	5	6	Nil
56	20	8320	03/02/2011	B	1					34	HEAD	25%	<1CM	-2	2	3hrs	NIL	13/3/11	35+4	11	2.3	5	6	Nil
57	24	8746	03/07/2011	UB	1					36	HEAD	50%	2CM	-2	5	6hrs	HEADACHE	9/3/2011	36+2	2	2.5	6	7	Nil
58	21	8912	18/03/2011	UB	1					32	BREECH	75%	3CM	-1	6	12hrs	NIL	19/3/11	32+1	1	1.4	4	5	Admission
59	26	9275	27/03/2011	B	1					34	HEAD	50%	1CM	-2	3	4hrs	NIL	10/4/2011	36	14	2.4	6	7	Nil
60	22	10028	04/06/2011	UB	3	1	1	1	YES	32	HEAD	75%	2CM	-1	5	10hrs	NIL	8/4/2011	32+2	2	1.6	3	5	Admission
61	21	10284	04/10/2011	UB	3	2	2		YES	34	HEAD	25%	<1CM	-2	2	2hrs	NIL	24/4/11	36	14	2.4	5	6	Nil
62	25	10532	16/04/2011	B	1					35	HEAD	25%	<1CM	-2	2	3hrs	NIL	13/5/11	37+3	17	2.8	4	7	Nil
63	23	10855	22/04/2011	B	2	1	1			33	HEAD	25%	<1CM	-2	2	2.5hrs	Nil	20/5/11	37	28	2.7	6	7	Nil
64	20	10996	27/04/2011	UB	1					32	HEAD	75%	3CM	-1	7	10hrs	DIZZINESS	27/4/11	32	SAMEDAY	1.3	3	4	Admission
65	20	11228	05/07/2011	B	1					35	HEAD	25%	<1CM	-2	1	2hrs	NIL	23/5/11	37+2	16	2.8	5	7	Nil
66	32	11402	05/12/2011	UB	2	1	1			32	HEAD	50%	1CM	-3	3	6hrs	NIL	19/5/11	33	7	2	4	6	Admission
67	26	11785	20/05/2011	UB	1					32	BREECH	50%	1CM	-2	3	3.5hrs	HEADACHE	15/6/11	35+5	26	2.4	5	6	Nil
68	30	11902	24/05/2011	UB	2	1	1			36	HEAD	75%	2CM	-2	5	12hrs	NIL	26/5/11	36+2	2	2.5	4	6	Nil
69	19	12198	06/04/2011	B	1					33	HEAD	50%	1CM	-3	3	6hrs	NIL	14/6/11	34+3	10	2.1	3	5	Admission
70	27	12385	06/07/2011	B	1					32	HEAD	25%	<1CM	-2	2	4hrs	NIL	18/6/11	33+4	11	1.8	4	5	Admission
71	26	12584	06/12/2011	UB	2	1	1		YES	34	HEAD	75%	2CM	-2	5	10hrs	HEADACHE	14/6/11	34+2	2	2	3	5	Admission
72	32	12890	20/06/2011	UB	4	3	2		YES	34	HEAD	50%	1CM	-2	3	6hrs	NIL	22/6/11	34+2	2	2.3	5	6	Nil
73	26	12998	25/06/2011	UB	2	1	1			33	HEAD	25%	<1CM	-2	2	4hrs	NIL	22/7/11	36+6	27	2.5	5	6	Nil
74	25	13225	07/03/2011	B	1					36	HEAD	50%	1CM	-2	3	6hrs	NIL	10/7/2011	37	7	2.5	4	6	Nil
75	22	13346	07/07/2011	UB	1					34	HEAD	25%	<1CM	-2	2	2.5hrs	NIL	19/7/11	35+5	12	2.4	5	6	Nil

76	28	14112	19/07/2011	UB	2	1	1		YES	28	BREECH	75%	3CM	-2	6	12hrs	TACHYCARDIA	19/7/11	28	SAMEDAY	1.2	3	4	Admission
77	25	14205	21/07/2011	UB	3	1	1	1		32	HEAD	75%	3CM	-1	6	10hrs	Nil	23/7/11	32+2	2	1.5	2	5	Admission
78	23	15073	29/07/2011	UB	2	1	1			30	BREECH	25%	1CM	-2	2	3hrs	NIL	5/9/2011	35+3	38	2.4	5	6	Nil
79	32	15301	08/04/2011	UB	3	2	1		YES	32	HEAD	50%	2CM	-2	4	4hrs	NIL	11/8/2011	33	7	1.8	4	5	Admission
80	22	15467	08/07/2011	UB	3	1	1	1		32	HEAD	25%	<1CM	-2	2	3hrs	NIL	29/9/11	35+1	22	2.3	4	6	Nil
81	23	16149	20/08/2011	B	1					30	HEAD	25%	1CM	-3	2	4hrs	NIL	20/9/11	34+3	31	2.2	5	6	Nil
82	24	16423	25/08/2011	B	2			1		32	HEAD	50%	1CM	-2	3	6hrs	NIL	9/9/2011	34+2	16	2.3	5	6	Nil
83	25	16820	09/01/2011	UB	3	2	2		YES	32	HEAD	75%	2CM	-3	5	10hrs	HEADACHE	7/9/2011	32+6	6	1.4	3	4	Admission
84	19	17013	09/04/2011	B	1					30	HEAD	25%	<1CM	-2	2	3hrs	NIL	10/10/2011	35+1	36	2.4	5	6	Nil
85	18	17215	09/09/2011	UB	1					32	HEAD	25%	<1CM	-2	2	3.5hrs	NIL	7/10/2011	36	28	2.4	5	6	Nil
86	27	17854	16/09/2011	UB	3	1	1	1		32	HEAD	25%	<1CM	-3	2	3hrs	NIL	14/10/11	36	28	2.5	5	6	Nil
87	25	18043	23/09/2011	UB	2	1	1		YES	32	HEAD	75%	3CM	-1	7	12hrs	TACHYCARDIA	24/9/11	32+1	1	1.4	3	4	Admission
88	20	18237	28/09/2011	B	1					34	HEAD	75%	1CM	-3	4	4hrs	NIL	4/10/2011	34+6	6	2Kg	5	6	Nil
89	31	18342	10/01/2011	UB	3	2	2		YES	34	HEAD	75%	3CM	-1	6	10hrs	HEADACHE	2/10/2011	34+1	1	1.9	3	5	Admission
90	25	18604	10/09/2011	B	1					32	HEAD	50%	1CM	-2	2	4hrs	NIL	27/10/11	34+4	18	2	2	5	Admission
91	18	18712	10/12/2011	B	1					34	HEAD	25%	<1CM	-3	2	3hrs	NIL	3/11/2011	37+1	22	2.9	6	8	Nil
92	31	18854	15/10/2011	UB	4	1	1	2		28	BREECH	75%	3CM	-1	6	12hrs	HEADACHE	17/10/11	28+2	2	1.2	3	4	Admission
93	18	18920	16/10/2011	B	1					36	HEAD	75%	1CM	-3	4	4hrs	NIL	21/10/11	36+5	5	2.4	5	6	Nil
94	19	19078	19/10/2011	UB	1					34	HEAD	50%	1CM	-3	3	8hrs	NIL	4/11/2011	36+2	16	2.6	5	7	Nil
95	30	19134	21/10/2011	UB	3	1	1	1		30	HEAD	75%	3CM	-1	6	8hrs	DIZZINESS	23/10/11	30+2	2	1.3	3	4	Admission
96	23	19198	23/10/2011	B	1					34	HEAD	25%	<1CM	-3	3	6hrs	NIL	11/11/2011	36+5	19	2.5	5	6	Nil
97	29	19251	25/10/2011	UB	3	1	1	1		33	HEAD	50%	1CM	-2	3	6hrs	NIL	15/11/11	37	21	2.8	6	7	Nil
98	19	19328	28/10/2011	B	2	1	1			34	HEAD	25%	<1CM	-3	2	5hrs	NIL	15/11/11	36+4	18	2.5	5	6	Nil
99	24	19382	29/10/2011	UB	2	1	1			34	HEAD	50%	1CM	-2	3	5hrs	NIL	7/11/2011	35+2	9	2.4	5	6	Nil
100	19	19550	11/02/2011	UB	1					36	HEAD	75%	2CM	-2	5	10hrs	HEADACHE	4/11/2011	36+2	2	2.5	5	6	Nil